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EXAMINER

YU, MELANIE J

ART UNIT PAPER NUMBER

1641

DATE MAILED: 02/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/087,730

Applicant(s)

DAVIS ET AL.

Examiner

Melanie Yu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-62 is/are pending in the application.
- 4a) Of the above claim(s) 37-55 and 57-62 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-36 and 56 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 April 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>3/02, 3/02</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election without traverse of group I, claims 1-36 and 56 in the reply filed on January 6, 2005 is acknowledged. Claims 37-55 and 57-62 have been withdrawn from consideration as being drawn to non-elected inventions.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-36 and 56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 3 are vague and indefinite because it is unclear if the fluid is displaced from a second to a first conduit or if the fluid is first displaced into the first conduit and then displaced into the second conduit.

Regarding claim 4, it is unclear whether the at least one sensor capable of detecting an air-liquid interface is the same as the at least one analyte sensor.

With respect to claim 13, it is vague as to whether the closeable valve comprises the dry sponge, flap and gelling polymer, or whether the closeable valve is selected from the group comprising the dry sponge, flap and gelling polymer.

Claim 29 is vague and indefinite because the type and amount of mechanical and electrical connections required for insertion into a reading apparatus are unclear.

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With respect to claim 34, the capability and localization of the microparticles is indefinite. It is unclear how the microparticles are required to interact with the analyte, and whether contact with the analyte is considered interaction. Furthermore, the localization of the microparticles to the sensors is unclear because the relation of the microparticles to the sensor is vague.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-3, 5-8, 12-21, 30, 31, 34-36 and 56 are rejected under 35 U.S.C. 102(e) as being anticipated by Kapur et al. (US 6,548,263).

Kapur et al. teach a single-use (col. 12, line 66-col. 13, line 4) cartridge comprising: a sample holding chamber for receiving and retaining a sample (capillary, 024, receives and retains a sample until pushed into the first conduit, 030, Fig. 8; col. 12, lines 34-45); a first conduit connected to the sample holding chamber (030 and 008, Fig. 8; col. 20, lines 40-48); at least one analyte sensor, wherein the sensor comprises an analyte-responsive surface and the surface is within the first conduit (008, Fig. 1b; col. 12, lines 46-56); a second conduit for retaining a fluid, the second conduit connected to the first conduit (032, Fig. 8; col. 20, line 64-col.21, line 4); a valve connected to an opening in the first conduit, wherein the valve is closed by contact with the sample (500, Fig. 36; col. 20, lines 48-52); means for inserting a single or plurality of air

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segments into the first and second conduit (740, Fig. 41; col. 20, lines 12-40; col. 31, lines 46-49; col. 33, line 65-col. 34, line 11), wherein the means comprises a plurality of electrodes operably connected to a current source (col. 28, lines 12-40); a pump capable of displacing the sample from the holding chamber into the first conduit, the pump further capable of displacing the fluid from the second conduit into the first conduit (740, Fig. 41; col. 20, lines 12-40); and a third conduit connecting the second conduit to an overflow chamber (300, Fig. 29 and 41; col. 28, lines 37-40).

Regarding claims 13-16, Kapur et al. teach a closable valve comprising a dry sponge coated with a fluid impermeable layer, a flap capable of blocking the valve and held open by a dry gelling polymer (col. 30, lines 40-65). Kapur et al. also teach at least one constriction to control fluid flow within the first and second conduits (col. 26, lines 28-53). Kapur et al. further teach the second conduit further comprising a valve responsive to hydrostatic pressure (col. 33, lines 43-47), and the valve comprising a constriction having a fluid-contacting surface comprising a hydrophobic surface (col. 26, lines 28-53).

With respect to claims 18, Kapur et al. teach the pump being an electrodynamic pump (electrokinetic pump; col. 28, lines 12-40).

Regarding claims 19-21, Kapur et al. teach an analyte-responsive surface comprising an antibody (col. 18, lines 30-63) and a portion of at least one conduit further comprises at least one dry reagent capable of dissolving in the fluid or sample (col. 48, lines 28-53), wherein the dry reagent is an antibody-enzyme conjugate (col. 58, lines 52-67).

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With respect to claims 30 and 31, Kapur et al. teach an analyte sensor formed on a substantially planar surface (col. 10, lines 1-6). Kapur et al. also teach a surface coating that decreases non-specific binding of a substance (col. 2, lines 40-43).

With respect to claims 34-36, Kapur et al. teach mobile magnetic microparticles comprising a magnetic field for localizing the microparticles adjacent to at least one sensor (600, Fig. 37; col. 34, line 61-col. 35, line 9). Kapur et al. further teach a filter element interposed between the sample holding chamber and the analyte sensor and adjacent to the sensor (filter-76,78,80, Fig. 13; sensor-82, Fig. 13).

Regarding claims 56, Kapur et al. teach the sample holding chamber further comprising a closure means (valve, col. 20, lines 48-52).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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4. Claims 4 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kapur et al. (US 6,548,263) in view of Zelin (Us 5,821,399).

Kapur et al., as applied to claims 1-3, teach a cartridge for sensing at least one analyte, but fail to teach at least one sensor capable of detecting an air-liquid interface.

Zelin teaches a cartridge comprising air segments inserted into conduits (col. 3, lines 34-42) and a conductivity sensor capable of detecting an air-liquid interface (col. col. 4, lines 40-67), in order to displace calibrating fluid and separate calibrating fluid from a blood test sample.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the cartridge of Kapur et al., a conductivity sensor as taught by Zelin, in order to ensure a constant volume of test fluid sample passing over the sensors to increase the consistency and reliability of the output measurements made by each sensor of the sensing device of the fluid system.

5. Claims 10 and 11 rejected under 35 U.S.C. 103(a) as being unpatentable over Kapur et al. (US 6,548,263) in view of Opalsky et al. (US 6,438,498).

Kapur et al., as applied to claim 1, teach a cartridge for sensing at least one analyte, but fail to teach a means for metering.

Opalsky et al. teach a means for metering involving a capillary stop in a first conduit in order to adequately fill a sensor channel (col. 10, lines 38-col. 11, line 10).

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the cartridge of Kapur et al., a means for metering as taught by Opalsky et al., in order to regulate the amount of volume entering the second conduit.

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6. Claims 22-26, 28-29 and 32-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kapur et al. (US 6,548,263) in view of Zier et al. (US 4,919,141).

Kapur et al., as applied to claims 1-3 and 20-21, teach a cartridge for sensing at least one analyte comprising a dry reagent being an antibody-enzyme conjugate, but fail to teach a specific enzyme.

Zier et al. teach an enzyme glucose oxidase (col. 3, lines 35-44), in order to coat a measurement electrode for an implantable sensor.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the cartridge of Kapur et al., an enzyme of glucose oxidase, in order to detect analyte in blood or tissue liquid.

With respect to claim 32, Zier et al. teach an enzyme and a substrate capable of regenerating a product consumed by contact with the at least one analyte sensor, whereby a signal from the sensor is increased (col. 7, line 63-col. 8, line 13).

Regarding claims 23 and 33, Zier et al. also teach a substrate of D-glucose (col. 7, line 63-col. 8, line 5).

With respect to claim Kapur et al. also fail to teach an analyte sensor being an immunosensor.

Zier et al. teach an immunosensor in order to amperometric measurements in body liquids (col. 4, lines 54-62).

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the cartridge of Kapur et al., an immunosensor as taught by Zier et al., in order to determine insulin amount values in a biological fluid of blood.



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Regarding claims 25, 28 and 29, Zier et al. teach the blood fluid comprising a substrate for an antibody-enzyme conjugate (col. 6, lines 4-8) wherein the substrate is cleaved to produce an electroactive product (col. 7, line 63-col. 8, line 13). Zier et al. also teach the analyte sensor being an amperometric sensor with a plurality of mechanical and electrical connections (col. 7, lines 45-62).

7. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kapur et al. (US 6,548,263) in view of Zier et al. (US 4,919,141) further in view of Grundig et al. (US 6,221,238).

Kapur et al. in view of Zier et al., as applied to claim 2, teach a fluid comprising a substrate for an antibody-enzyme conjugate wherein the substrate is cleaved to produce an electroactive product, but fail to teach the substrate being ferrocene.

Grundig et al. teach a ferrocene substrate in order to provide a redox-active label of an antigen (col. 1, lines 58-62).

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the cartridge of Kapur et al. in view of Zier et al., a ferrocene substrate as taught by Grundig et al., in order to modify increase the sensitivity of amperometric indication of an electrode comprising glucose oxidase.

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Yu whose telephone number is (571) 272-2933. The examiner can normally be reached on M-F 8:30-5.

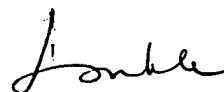
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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02/07/05